UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,939	05/30/2001	Douglas A. Amorese	10010791-1	8714

7590 08/25/2003

AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,939	AMORESE ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20 and 22-41* is/are pending in the application.

4a) Of the above claim(s) *22-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20 and 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 19 December 2002 in which claims 1-3,8, 10-13 and 15-19 were amended, claims 4 and 21 were canceled and claims 38-41 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 21 August 2002 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. However, the arguments are addressed as they relate to the instant rejections. New grounds for rejection necessitated by amendment are discussed.

Claims 1-3, 5-20 38-41 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5-9, 11-14 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (U.S. Patent No. 6,060,288, issued 9 May 2000).

Regarding Claim 1, Adams et al disclose a polynucleotide array comprising a first set of features comprising polynucleotides at least 400 nucleotides in length (i.e. 1kb target sequence hybridized to primer) and a second set of features having polynucleotides no more than 100 nucleotides in length (i.e. non-extended primers, (Column 2, lines 19-23 and Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 5, Adams et al disclose the array wherein the first polynucleotides are from enzymatic processing (i.e. primer extension to produce complement of the target) and the second polynucleotides are synthetic (Column 16, lines 40-60). While Adams teaches the claimed process for making the first and second polynucleotides, it is noted that the claimed process for making the polynucleotides does not limit the polynucleotides.

The courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 6, Adams et al disclose the array wherein the first molecules have a length of at least 500 nucleotides (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 7, Adams et al disclose the array wherein the first molecules have a length of at least 1,000 nucleotides (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 8, Adams et al disclose the array wherein the polynucleotide length excludes any stilt portion i.e. the target sequence is sonicated to produce fragments (Example 1, Column 22, lines 40-47) and the primers comprise 10 to 50 nucleotides (Column 2, lines 19-23).

Regarding Claim 9, Adams et al disclose the array wherein the features are arranged in a rectangle and the second set features are at least in the corners of the rectangle i.e. each area comprises a primer pair (Column 10, lines 9-40 and Fig. 2).

Regarding Claim 11, Adams et al disclose the array wherein at least 70% of a sequence of second polynucleotide sequence is not contained within a sequence of a first polynucleotide sequence i.e. the second polynucleotide (i.e. primer) is not contained within the first polynucleotide (i.e. target) (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 12, Adams et al disclose the array wherein at least 70% of a sequence of second polynucleotide sequence is not contained within a sequence of a first polynucleotide sequence i.e. the second polynucleotide (i.e. primer) is not contained within the first polynucleotide (i.e. target) (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 13, Adams et al disclose the array wherein the none of the second polynucleotide sequence is contained within a first polynucleotide sequence i.e. the second primer is not contained within the first target (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 14, Adams et al disclose the array wherein the sequence of a second polynucleotide is contained within a first polynucleotide sequence i.e. overlapping primers as illustrated in Fig 3 e.g. primer 231a overlaps primer 231b (Column 12, lines 40-61 and Fig. 3).

Regarding Claim 39, Adams et al disclose the array wherein at least 70% of a sequence of each of second polynucleotide sequence is not contained within a sequence of a first polynucleotide sequence i.e. the second polynucleotide (i.e. primer) is not contained within the first polynucleotide (i.e. target) (Example 1, Column 22, lines 40-56 and Fig. 2).

Regarding Claim 40, Adams et al disclose the array wherein at least 70% of a sequence of each of second polynucleotide sequence is not contained within a sequence of any of a first polynucleotide sequence i.e. the second polynucleotide (i.e. primer) is not contained within the first polynucleotide (i.e. target) (Example 1, Column 22, lines 40-56 and Fig. 2).

Response to Arguments

4. Applicant argues that because the claims have been amended to recite that both the first and second polynucleotides are single stranded, Adams et al do not anticipate the instant invention. The argument has been considered but is not found persuasive because the instant claims are drawn to features which "has" single stranded first and second polynucleotide molecules. The open claim language "has" encompasses the polynucleotides of Adams et al which have a single stranded polynucleotide hybridized to the primer (Example 1, Column 22, lines 40-56 and Fig. 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenchik et al (U.S. Patent No. 6,087,102, issued 11 July 2000) as defined by Stewart, R. (A Few Words about DNA and Chromatin, dissertation, 1997, page 2).

Regarding Claim 1, Chenchik et al disclose a polynucleotide array comprising a first and second set of multiple features each comprising polynucleotides of differing length i.e. collected from fractions ranging from 10^3 daltons to 10^6 daltons (Column 8, lines 15-21) and they disclose the polynucleotides are arranged according to size (Claims 8-12). It was well known in the art at the time the claimed invention was made that the average weight of a single nucleotide (A, T, C and G) is 307.5 daltons as taught by Stewart (page 2). The length of Chenchik's polynucleotides can be determined using the known weight of nucleotides i.e. the 10^3 dalton fraction provides polynucleotides of about 10 nucleotides and the 10^6 dalton fraction provides polynucleotides of about 10,000 nucleotides. Therefore, the polynucleotides of Chenchik et al, collected from fractions having weights ranging from 10^3 daltons to 10^6 daltons. Chenchik et al collect the fractions and arrange the fragments from the fractions on the array according to their size (Abstract).

Furthermore, Chenchik et al provide an example wherein the array comprises 100 fraction separated sizes wherein the shortest has about 200 and the longest has about 12,000 nucleotides (Example 2, Column 14, lines 45-48). While they do not specifically teach a polynucleotide of no more than 100 nucleotides, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the fractions collected by Chenchik et al would contain fragments of no more than 100 nucleotides based on their teaching of the range of sizes provided within one fraction (Column 8, lines 13-21). Alternatively, it would have been obvious to one of ordinary skill to modify polynucleotides of Chenchik et al and the provide polynucleotides of no more than 100 nucleotides to thereby detect expressed products of small size as they desire (Column 1, lines 38-43).

Regarding Claim 6, Chenchik et al disclose the array wherein the first molecules have a length of at least 500 nucleotides (Column 14, lines 37-51).

Regarding Claim 7, Chenchik et al disclose the array wherein the first molecules have a length of at least 1,000 nucleotides (Column 14, lines 37-51) but they do not specifically teach

a polynucleotide of no more than 80 nucleotides, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the fractions collected by Chenchik et al would contain fragments of no more than 80 nucleotides based on their teaching of the range of sizes provided within one fraction (Column 8, lines 13-21). Alternatively, it would have been obvious to one of ordinary skill to modify polynucleotides of Chenchik et al and the provide polynucleotides of no more than 100 nucleotides to thereby detect expressed products of small size as they desire (Column 1, lines 38-43).

Regarding Claim 8, Chenchik et al disclose the lengths exclude stilt portions i.e. Chenchik et al disclose the target molecules (Column 8, lines 12-39) but do not teach the polynucleotides comprise stilts. Therefore, the polynucleotide length excludes a stilt portion.

Regarding Claim 9, Chenchik et al disclose the array wherein the array features are arranged in a rectangle with second set features at least at the corners i.e. the smaller polynucleotides are at least in the upper corners (Column 5, lines 63-67 and Fig. 1)

7. Claims 2, 3, 10 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al (U.S. Patent No. 6,060,288 issued 9 May 2000).

Regarding Claims 2 and 3, Adams et al teach a polynucleotide array comprising a first set of features comprising polynucleotides at least 400 nucleotides in length (i.e. 1kb target sequence hybridized to primer) and a second set of features having polynucleotides no more than 100 nucleotides in length (i.e. non-extended primers, Column 2, lines 19-23) (Example 1, Column 22, lines 40-56 and Fig. 2) and they teach the array comprises primers for multiplex diagnosis i.e. primers which extend in the presence of any one of numerous different pathogens (Column 5, lines 13-27) but they do not teach a ratio of short to long polynucleotides. However, it would have been obvious to one of ordinary skill in the art at the time the claimed

invention was made, based on experimental design wherein expressed sequences are of interest, to provide an array comprising the claimed ratios. For example, an experiment designed to analyze expressed sequences of at least 400 nucleotides, an array comprising mostly sequences of at least 400 nucleotides would provide optimal analysis of the 400 nucleotide + sequences. Therefore, one skilled in the art would have been motivated to design the array having a short (less than 100) to long (at least 400) polynucleotide ratio of at least 1:10 or 1:20 to thereby optimize experimental condition and maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 10, Adams et al teach a polynucleotide array comprising a first set of features comprising polynucleotides at least 400 nucleotides in length (i.e. 1kb target sequence hybridized to primer) and a second set of features having polynucleotides no more than 100 nucleotides in length (i.e. non-extended primers, Column 2, lines 19-23) (Example 1, Column 22, lines 40-56 and Fig. 2) but they do not teach a spacing between the first and second polynucleotides. However, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to space of the polynucleotides based on experimental design to thereby optimize experimental results.

Regarding Claim 15, Adams et al teach a kit comprising a polynucleotide array comprising a first set of features comprising polynucleotides at least 400 nucleotides in length (i.e. 1kb target sequence hybridized to primer) and a second set of features having polynucleotides no more than 100 nucleotides in length (i.e. non-extended primers, Column 2, lines 19-23) (Column 6, lines 9-28) and they teach a method of using the kit components wherein control polynucleotides complementary to polynucleotides on the array are added along with the sample as a positive control (Column 12, lines 30-36) but they do not specifically teach their kit comprises the polynucleotide controls. It would have been obvious

to one of ordinary skill in the art at the time the claimed invention was made to modify the kit by further including the control polynucleotides for the obvious benefit of having all components for their method combined into a kit format.

Regarding Claim 16, Adams et al teach the control polynucleotides are complementary to polynucleotides on the array are added along with the sample as a positive control (Column 12, lines 30-36).

Regarding Claim 17, Adams et al teach the control polynucleotides are labeled i.e. produce a signal (Column 12, lines 30-36).

Regarding Claims 18 and 19, Adams et al teach the array comprises primers for multiplex diagnosis i.e. primers which extend in the presence of any one of numerous different pathogens (Column 5, lines 13-27) but they do not teach a ratio of short to long polynucleotides. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, based on experimental design wherein expressed sequences are of interest to provide an array comprising the claimed ratios. For example, an experiment designed to analyze expressed sequences of at least 400 nucleotides, an array comprising mostly sequences of at least 400 nucleotides would provide optimal analysis of the 400 nucleotide + sequences. Therefore, one skilled in the art would have been motivated to design the array having a short (less than 100) to long (at least 400) polynucleotide ratio of at least 1:10 or 1:20 to thereby optimize experimental condition and maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 20, Adams et al teach the kit comprises instructions (Column 6, lines 22-24). However, the courts have stated that printed matter e.g. kit instructions does not distinguish over the prior art teaching of the structure e.g. kit components.

A combination including printed matter and structure wherein the features of structure are old and the relationship of the printed matter to the structure is old, so that any novelty is in the meaning or significance of the words used in the printed matter, is not patentable as a manufacture in the sense of 35 U.S.C. 101. Boyle et al. v. Ladd, 138 USPQ 289 (D.C.D.C. 1963); Ex parte Gwinn, Jr., 112 USPQ 439 (1955); Conover v. Coe, 69 App. D.C. 144, 99 F.2d 377, 38 USPQ 309 (1938), and In re Russell, 18 CCPA 1184, 48 F.2d 668, 9 USPQ 181 (1931).

In re Gulack, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

I*n re Miller*, (CCPA 1969) 164 USPQ 46, which has as the disclosed invention a set of measuring devices that contain a set of printed indicia upon them referring to fractionated measurements, as well as a legend to such printing, it is stated that "the fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio..." (page 5). This suggests that in order for printed matter to be considered patentable subject matter, there must exist a new and unobvious *functional* relationship between the printed matter and the other elements of the claim. However, in the case of instant claim 20, no such functional relationship exists. The printed matter merely contains instructions for one use of components of a kit, and no functional relationship exists between the instructions and the other elements of the kit because the components of the kit are capable of functioning without the printed matter.

Response to Arguments

8. Applicant reiterates the argument presented above regarding the rejection under 35 U.S.C. 102. The arguments have been considered but are not found persuasive as discussed above (see ¶ 4).

New Grounds of Rejection Necessitated by Amendment

9. Claims 1-3, 5-10, 14, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999).

Regarding Claim 1, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5). Bao et al teach the cDNA target elements range from about 100 nucleotides which clearly suggests that the microarray comprises cDNA target elements of no more than 100 nucleotides. Furthermore, they teach that one of ordinary skill would adjust the lengths to optimize hybridization for any given hybridization (Column 8, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cDNA target elements of Bao et al and to provide the microarray with target elements of no more than 100 nucleotides as suggested by Bao et al (Column 8, lines 45-48) to thereby optimize the hybridization based on the desired procedure as taught by Bao et al (Column 8, lines 16-26).

Regarding Claims 2 and 3, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5) but they do not teach a ratio of short to long polynucleotides. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, based on experimental design wherein expressed sequences are of interest, to provide an array comprising the claimed ratios. For example, an experiment designed to analyze expressed sequences of at least 400 nucleotides, an array comprising mostly sequences of at least 400 nucleotides would provide optimal analysis of the 400 nucleotide + sequences. Therefore, one skilled in the art would have been motivated to design

the array having a short (less than 100) to long (at least 400) polynucleotide ratio of at least 1:10 or 1:20 to thereby optimize experimental condition and maximize experimental results.

Regarding Claim 5, Bao et al disclose the array wherein the first polynucleotides are from enzymatic processing (i.e. cloning) and the second polynucleotides are synthetic (i.e. obtained from commercial sources) (Column 8, lines 445-65). While Bao et al teaches the claimed process for making the first and second polynucleotides, it is noted that the claimed process for making the polynucleotides does not limit the polynucleotides.

Regarding Claim 6, Bao et al disclose the array wherein the first polynucleotides have a length of at least 500 nucleotides (Column 8, lines 55-58).

Regarding Claim 7, Bao et al disclose the array wherein the first polynucleotides have a length of at least 1100 nucleotides (Column 8, lines 55-58). Bao et al teach the cDNA target elements range in size from about 100 nucleotides which clearly suggests that the microarray comprises cDNA target elements of no more than 800 nucleotides. Furthermore, they teach that one of ordinary skill would adjust the lengths to optimize hybridization for any given hybridization (Column 8, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cDNA target elements of Bao et al and to provide the microarray with target elements of no more than 80 nucleotides as suggested by Bao et al (Column 8, lines 45-48) to thereby optimize the hybridization based on the desired procedure as taught by Bao et al (Column 8, lines 16-26).

Regarding Claim 8, Bao et al disclose the lengths exclude stilt portions i.e. Bao et al teach the polynucleotides are attached to the support (Column 11, lines 50-54) and do not teach the polynucleotides comprise stilts. Therefore, the polynucleotide length excludes a stilt portion.

Regarding Claim 9, Bao et al disclose the array wherein the features are arranged in a rectangle (Fig. 1A).

Regarding Claim 10, Bao et al disclose the features are arranged in lines (Fig. 1A) with at least some of the lines including features of both first and second sets i.e. the cDNA and genomic DNA target elements are interspersed (Column 10, lines 31-38).

Regarding Claim 14, Bao et al disclose the array wherein the sequence of the second polynucleotide is contained within the first polynucleotide i.e. cDNA is contained within genomic DNA from (Column 10, lines 31-35 and Claim 5).

Regarding Claim 38, Bao et al disclose the microarray wherein features have the same polynucleotide i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10).

Regarding Claim 41, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5) and wherein each feature contains only one sequence i.e. array manufacture via deposition of a different nucleic acid at each spot (Column 9, line 66-Column 10, line 10). Bao et al teach the cDNA target elements range from about 100 nucleotides which clearly suggests that the microarray comprises cDNA target elements of no more than 100 nucleotides. Furthermore, they teach that one of ordinary skill would adjust the lengths to optimize hybridization for any given hybridization (Column 8, lines 16-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cDNA target elements of Bao et al and to provide the microarray with target elements of no more than 100 nucleotides as suggested by Bao et al (Column 8, lines 45-48) to thereby optimize the hybridization based on the desired procedure as taught by Bao et al (Column 8, lines 16-26).

10. Claims 11-13, 15-20 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al (U.S. Patent No. 6,251,601, filed 2 February 1999) in view of CLONTECHniques (July 2000).

Regarding Claims 11-13 and 39-40, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5) but they do not teach the array comprising a second set of features wherein the sequences of the second set of features is not within the first polynucleotide sequence. However, Clontech teaches a similar microarray comprising a second set of polynucleotides wherein the second set comprises control sequences not found in the first set of polynucleotides (right column and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 15, Bao et al disclose a microarray comprising a first set of features having single-stranded polynucleotides of at least 400 nucleotides (i.e. genomic DNA target elements, Column 8, lines 55-58) and a second set of features having single-stranded polynucleotides of about 100 nucleotides (i.e. cDNA target elements, Column 8, lines 45-48) wherein the microarray comprises both genomic DNA and cDNA target elements (Column 10, lines 31-35 and Claim 5). Bao et al teach the cDNA target elements range from about 100 nucleotides which clearly suggests that the microarray comprises cDNA target elements of no

more than 100 nucleotides. Furthermore, they teach the microarray and reagents for using the array combined into a kit format (Column 14, line 63-Column 15, line13) but they do not specifically teach the reagents comprise polynucleotide controls at least 70% complementary to the second polynucleotides. However, microarray kits comprising control probes complementary to control polynucleotides on the microarray were well known in the art at the time the claimed invention was made as taught by Clontech. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the control probes of Clontech to the kit of Bao et al for the expected benefit of providing means for troubleshooting hybridizations as taught by Clontech (last paragraph).

Regarding Claim 16, Clontech teaches that the control probes are complementary to control polynucleotides on the microarray (last paragraph).

Regarding Claim 17, Clontech teaches that the control probes are labeled (last paragraph).

Regarding Claim 18, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 10/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 19, Clontech teach that the ratio of first set of features (i.e. target-specific) to the second set of features is at least 20/1 (i.e. the microarray comprises two control spots, Fig. 1 and last paragraph).

Regarding Claim 20, Clontech teaches the kit comprises instructions (right column).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 21, 2003